I. The Rejection of Claims 1-21 Under 35 U.S.C. 102: Claims 1-7, 9-10, 11-12 and 14-21 over Roth (US Patent No. 6,096,175); Claims 1-4, 8, 11-15 and 20-21 over Moller et al. US Patent No. 5,772,864); and Claims 1-4, 6, 8-9, 11-15 and 17 over Reed et al. (US Patent No. 6,197,013) Should be Withdrawn.

Anticipation under 35 U.S.C. §102 requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). *In re Robertson,* 49 USPQ2d 1949 (Fed. Cir. 1999). The rejection of claims 1-21 under section 102 over at least one of the following references: Roth, Moller and Reed, should be withdrawn because the references fail to disclose every element of claims 1-21 individually and, therefore, fail to anticipate the claimed invention.

The Patent Office incorrectly states in the office action that Roth discloses all elements of claims 1-7, 9-12 and 14-21. Since Roth fails to disclose every element it cannot anticipate the present invention. Among the reasons why Roth fails to anticipate the claimed invention is that Roth fails to disclose the fabrication of a stent that is radially expansible or "capable of radially expanding" (as claim 1 recites). In item 3 of the Office Action, the Examiner alleges that Roth discloses this element on Col. 2, lines 22-24, but this section only recites, as part of the background, that "many significant aneurysms take place in the Circle of Willis and approaching blood vessels." The apparatus disclosed in Roth is referred to as "**rolled sheet** stents" (emphasis added). Roth, col. 3, line 16. Furthermore, Roth explains in the detailed description section that the stent is formed so that "when rolled and released, it resiliently unrolls and expands to . . ." Roth, col. 4, lines 30-34. This description is of a rolled sheet that increases diameter by simply unraveling or reducing the amount of overlap of the sheet. In Roth, the diametric change of the rolled stent is not the result of any geometric shape change in the rolled sheet, itself. This is not the radial expansion that is an element of the claimed invention. The claimed invention is a closed cylindrical stent, which when undergoing expansion expands radially outward. Accordingly, Roth fails to anticipate the claimed invention.

In sharp contrast to Roth, the present claims recite stents "capable of radially expanding," which is well known in the implantable medical device arts to mean a device that undergoes a

diametric change because of a geometric change or deformation by either plastic, elastic, shape memory or pseudoelastic deformation. Since there is no geometric change or deformation of the rolled sheet stent in Roth, one skilled in the art would understand that the rolled sheet stent is **not** "capable of radially expanding."

The rejection of claims 1-4, 8, 11-15 and 20-21 under section 102(b) over Moller *et al.* should be withdrawn because it fails to disclose all the elements of the claimed invention. Since Moller *et al.* fails to disclose every element it cannot anticipate the present invention. Moller *et al.* fails to anticipate the claimed invention because while disclosing methods of forming a metallic stent, Moeller *et al.* fails to disclose methods that include vacuum deposition. The Examiner incorrectly alleges that Moller *et al.* discloses deposition by vacuum deposition. In particular, the Examiner points to various sections of the specification in Moller *et al.*, but none of the cited sections discloses vacuum deposition. Col. 3, lines 30-31 and 44-48 only generally discusses deposition of material into the reverse image of the mandrel. Whereas, Col. 4, lines 38-40 discusses a specific deposition method, electro-deposition. Furthermore, Moller *et al.* discloses the use of electrochemical deposition (ECD) in discussing their preferred embodiment. The ECD process is defined as "a process for deposition of metal/metal alloys or metal compounds on a base material (mandrel) by electrolysis from aqueous solution, organic solution or salt melts." Col. 7, lines 38-41. Those skilled in the art would understand that electrochemical deposition is starkly different from the claimed vacuum deposition processes, which does not rely upon any electrolysis from solution or salt melts. Accordingly, Moller *et al.* fails to anticipate the claimed invention.

The rejection of claims 1-4, 6, 8-9, 11-15 and 17 under section 102(e) over Reed *et al.* should be withdrawn because it fails to disclose all the elements of the claimed invention. Since Reed *et al.* fails to disclose every element it cannot anticipate the present invention. Reed *et al.* is concerned with a stent apparatus that includes a probe on its surface and only generally mentions the deposition of metal, including using a combination of evaporation, sputtering and electroplating, and electroless deposition methods, but fails to teach vacuum deposition for fabricating a radially expandable stent. In support of the various contemplated deposition methods, Reed *et al.* simply cites to S.K. Ghandhi, "VLSI Fabrication Principles," John Wiley and Sons (1981) and S.M. Sze, "Semiconductor Sensors," John Wiley and Sons (1994), but fails

to specifically teach vacuum deposition. The sections of the specification cited by the Examiner fail to support the allegation that Reed *et al.* does disclose the claimed vacuum deposition method. Col. 9, lines 44-54 only discloses RF-magnetron sputtering or chemical vapor deposition methods for coating a silicon surface with a sacrificial layer. Col. 10, lines 10-12 and 66-67 discuss recoating silicon wafers with a sacrificial layer and metal layers and coating a mandrel with a conformal layer with a list of techniques: electroplating, electroless deposition, evaporation, or others. These disclosures fail to disclose a vacuum deposition method for depositing the stent-forming material having mechanical properties sufficient to permit radial expansion of the formed endoluminal stent, as presently claimed in the pending claims. Since all the elements of the claimed invention are not present in Reed *et al.*, it fails to anticipate the claimed invention.

Based on all of the foregoing arguments, Applicants respectfully request the Examiner to withdraw the section 102 rejections based on the cited art.

II. Amended Claims 1-8, 10-26 Patentably Define Over the Art Of Record

Claims 1-8, 10-26 patentably define the inventive method as including vacuum deposition onto a substrate having a shaped or continuously curved exterior surface. Thus, the substrate may be cylindrical or tubular, or have other geometric shaped in which there is a continuously curved exterior deposition surface. Neither the Roth nor the Moeller reference teaches deposition onto a curved substrate surface. Reed does, however, suggest that fabricating a "cylindrical mandrel with probes on the surface" is possible by "employing micro EDM techniques on a metal tube or rod" then the "mandrel is coated (by electroplating, electroless deposition, evaporation or other techniques) by a conformal layer of metal." Col 10, lines 62 to Col 11, line 1. Reed also further suggests that "Holes for the lattice pattern 10, can be made with EDM, or a selective deposition technique could be used which results in metal deposition only where it is wanted. After dissolving or otherwise removing the mandrel, the apparatus is released and ready for use." Col 11, lines 1-5.

First and foremost, Reed refers to the disparate deposition technologies of electroplating and electroless deposition, both of which are wet-processes conducted in liquid bath environments like Moeller, or evaporation, which is a sublimation process conduced in a vacuum

or other "techniques" which could be understood to include both liquid or vacuum techniques known in the semiconductor arts. Reed's teaching, therefore, is nothing more than a shotgun approach to suggesting the possibility that some type of deposition process ***may*** work, without providing any guidance as to how to apply any specific technique, the conditions under which a specific technique ***might*** be followed, or the predictability of success of any particular deposition method for obtaining "these apparatus" referred to in Col. 10, line 62 of Reed. Other than these extremely generally statements, there Reed is devoid of any teaching that would suggest to one of ordinary skill in the art that the resulting endoluminal stent was capable of radial expansion by geometric deformation as presently claimed.

At most, Reed may provide to one of skill in the art the suggestion to try. However, in order to fabricate by vacuum deposition onto a cylindrical substrate an endoluminal stent which is capable of radial expansion by geometric deformation, as Applicant's have accomplished and as demonstrated to the Examiner's at the Examiner's Interview on October 3, 2002, would unquestionably require a significant amount of undue experimentation to achieve the requisite material properties necessary for a radially expandable device.

Moreover, while Reed may offer a suggestion to try vacuum deposition of a stent-forming onto a cylindrical mandrel, Reed fails to teach or even remotely suggest that the material properties of the resulting endoluminal stent could be controlled during vacuum deposition in such a manner as to yield a radially expandable stent.

Accordingly, Applicant respectfully submits that neither Roth, Reed or Moeller anticipate the invention claimed in presently pending claims for purposes of 35 U.S.C. §102, nor do Roth, Reed nor Moeller, taken alone, or in combination render the presently claimed invention obvious under 35 U.S.C. §103 for the reasons stated above.

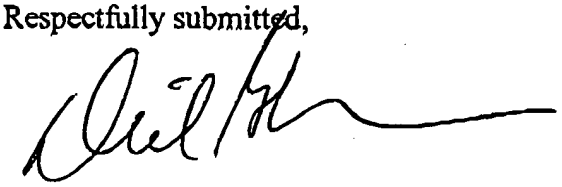
Summary

According to the arguments presented above, the applicants respectfully submit that the cited references fail to anticipate or render obvious the present invention and submit that pending claims 1-8, 10-21 and new claims 22-26 are allowable over the art cited and that of record. No new matter has been introduced by the amendments presented herein, and the antecedent support

for subject matter of new claims 22-26 may be found at Page 8, lines 4-12, Page 10, lines 4-16 and Page 12, lines 1-17.

Should the Examiner require any further information or wish to discuss any aspect of this Response, the Examiner is encouraged to telephone the undersigned at the telephone number set forth below.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES

1. A method of manufacturing an endoluminal stent capable radially expanding from a first diameter to a second diameter, comprising the steps of:

a. providing a substrate having [an] a continuously curved exterior surface capable of accommodating metal deposition thereupon;

b. vacuum depositing a stent-forming metal onto the substrate [by a vacuum deposition method];

c. defining a plurality of openings passing through the deposited stent-forming metal on the substrate, the plurality of openings forming geometric deformation regions permitting radial expansion of the endoluminal stent; and

d. removing the substrate from the radially expandable endoluminal stent formed thereupon.

Claim 9. Cancelled.

11. A method of making an implantable medical device, comprising the steps of:

(a) providing a substrate having a shaped exterior surface capable of accommodating metal deposition thereupon;

(b) vacuum depositing a biocompatible material onto the shaped exterior surface of the substrate[, thereby forming the implantable medical device] while controlling formation of heterogeneities in the biocompatible material;

(c) forming the implantable medical device in the deposited biocompatible material; and

(d) removing the substrate from the formed implantable medical device.

12. The method according to Claim 11, wherein step (a) further comprises the step of providing a substrate having a [three-dimensional] curved exterior surface.

13. The method according to Claim 12, wherein the [three-dimensional] curved exterior surface is generally cylindrical in shape.

14. The method according to Claim 11, wherein step [(b)] (c) further comprises the step of selective deposition of the biocompatible material onto the substrate.

Claim 22 (New) The method according to Claim 11, wherein step (c) further comprises the step of defining a pattern of openings passing through the deposited biocompatible material, the pattern of a plurality of openings defining deformation regions of the biocompatible material capable of undergoing geometric deformation thereby enlarging the pattern of a plurality of openings.

Claim 23 (New) The method according to Claim 11, wherein step (b) further comprises the step of controlling heterogeneities in the stent-forming metal during vacuum deposition.

Claim 24 (New) The method of Claim 23, wherein the step of controlling heterogeneities further comprises the step of controlling at least one of grain size, grain phase, grain material composition, stent material composition and surface topography during vacuum deposition.

Claim 25. (New) The method of Claim 23, wherein the step of controlling heterogeneities further comprises the step of defining polar and non-polar binding sites for binding blood plasma proteins.

Claim 26. (New) The method of Claim 11, wherein step (b) further comprises the step of controlling at least one of fatigue life, corrosion resistance, tensile strength and yield strength of the vacuum deposited biocompatible material.